Rep. Edward J. Markey
Statement of Introduction of
The "Fair Access to Clinical Trials (FACT) Act"
October 7, 2004

Mr. Speaker, I rise today to introduce the Fair Access to Clinical Trials (FACT) Act. This bill is designed to ensure that the public has complete and accurate information about the drugs and devices they use.

Recent revelations in the press and in the oversight hearings conducted by the Energy and Commerce Committee's Oversight and Investigations Subcommittee have raised serious concerns that some companies in the pharmaceutical and medical device industries have failed to properly disclosed important information from the public about the safety of certain drugs or medical devices. For example, there is now evidence that several pediatric anti-depressant trials that produced important new adverse information about the safety of certain drugs were not released to the public. The public is now demanding to know why these trials never saw the light of day. Although much attention has focused on disclosure problems involving the effects of certain anti-depressants on young people, the problem of selective disclosure and publication is not limited to a specific type of drug or scenario -- the same concerns exist whether we are talking about drugs to treat depression, heart disease or arthritis, or even a medical device that would be implanted into the human body.

I am sure that some clinical trials do not become part of the medical literature for innocent reasons. But we cannot ignore the possibility that some studies were and continue to be intentionally buried by companies who are worried about the impact of a negative trial on their bottom line. Regardless of the motivation, however, the fact remains that we don't know what trials are currently being conducted, so it is impossible to determine whether the companies and researchers are actually telling us the whole truth about their drugs and devices or whether they are painting a distorted picture of their products by picking and choosing which trials they want to reveal.

This creates two huge problems.

The first is that in order for doctors to make good medical decisions and provide their patients with the best possible care, they need to have access to complete and sound scientific data.

The second is that when people enroll in a clinical trial they give up a certain control of their own personal medical decisions, willingly taking experimental drugs and subjecting themselves to potential harm in the belief that their participation in the studies will add to the advancement of medical knowledge and potentially unlock the secrets of disease. But if a researcher or a company that sponsors a trial does not publicize the results, the knowledge gained from putting those participants at risk remains forever

buried in some researcher's computer. That information will not be available to doctors, or to other medical researchers, who could use it.

In order to ensure that clinicians have all the information they need in order to make sound medical decisions, uphold the ethical responsibility to patients and protect public health, I am proud to join with my the gentleman from California, Mr. Waxman, to introduce the Fair Access to Clinical Trials (The FACT Act) a bill to create a mandatory, public, federal registry of all clinical trials.

The FACT act will require researchers to register their clinical trials in a federal registry before starting them and report the results of those trials at the conclusion. The federal database will include both federal-funded and privately-funded clinical trials so that clinicians, patients and researchers will be able to know the universe of clinical trials on a particular drug and have access to the results of those trials. Our bill also establishes strong enforcement mechanisms, including monetary penalties of up to $10,000 per day for manufacturers who refuse to comply.

The registry established under the bill is intended to meet all of the minimum criteria for a trial registry set out by the International Committee of Medical Journal Editors, and will satisfy the American Medical Association's call for the results of all clinical trials to be publicly available to doctors and patients. Our legislation has been endorsed by the New England Journal of Medicine and the Elizabeth Glaser Pediatric AIDS Foundation.

The FACT act will ensure that patients have the tools they need to make informed decisions, maintain the integrity of the medical community, and protect the health of their patients and our families.

I look forward to working with everyone concerned about this important issue so that we end up with a system that preserves a robust system of research and ensures robust system of disclosure.